



DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2021-0182]

Qualification of Drivers; Exemption Applications; Narcolepsy

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of denial.

SUMMARY: FMCSA announces its decision to deny the application from one individual who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with either a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to control a CMV.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcamedical@dot.gov, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number,

FMCSA-2021-0182, in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

II. Background

On December 16, 2021, FMCSA published a *Federal Register* notice (86 FR 71537) announcing receipt of an application from one individual with a diagnosis of narcolepsy and requested comments from the public. The individual requested an exemption from 49 CFR 391.41(b)(8) which prohibits operation of a CMV in interstate commerce by persons with either a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to control a CMV. The public comment period closed on January 18, 2022, and one comment was received.

FMCSA has evaluated the eligibility of the applicant and concluded that granting an exemption would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(8). A summary of the applicant’s medical history related to the narcolepsy exemption request

was discussed in the December 16, 2021, *Federal Register* notice and will not be repeated here.

The Agency considered information from the 2009 Evidence Report, “Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety,” and the January 2010 Medical Review Board (MRB) recommendation that individuals with narcolepsy be ineligible for a commercial driver’s license, even with treatment. A copy of the Evidence Report is included in the docket.

Narcolepsy is a chronic neurological disorder caused by autoimmune destruction of hypocretin-producing neurons inhibiting the brain’s ability to regulate sleep-wake cycles normally. Persons with narcolepsy experience frequent excessive daytime sleepiness, comparable to how individuals without narcolepsy feel after 24 to 48 hours of sleep deprivation, as well as disturbed nocturnal sleep, which is often confused with insomnia. See National Institutes of Health Narcolepsy Fact Sheet at <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet>.

The 2009 Evidence Report, “Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety,” addressed whether or not individuals with narcolepsy are at an increased risk for motor vehicle crashes; whether or not currently recommended treatments for narcolepsy reduce the risk for motor vehicle crashes; and the impact of various medication therapies for narcolepsy on driver safety.

The evidence report reviewed studies from the available literature and evaluated outcomes on measures of Excessive Daytime Sleepiness (EDS), cataplexy, event rate, measures of cognitive and psychomotor function, and driving performance. The currently available direct and indirect evidence supports the contention that drivers with narcolepsy are at an increased risk for a motor vehicle crash when compared to otherwise similar individuals who do not have the disorder. The direct evidence from three crash studies

conducted of non-CMV drivers showed that individuals with narcolepsy are at an increased risk for a crash compared to individuals who do not have narcolepsy. The indirect evidence from studies of driving tests and driving simulation examined factors associated with simulated driving outcomes such as driving performance, tracking error, fewer correct responses, and more instances of going out of bounds compared to healthy controls. While there are limitations in the quality of the studies that examined direct crash risk, both the direct and indirect studies showed a strong effect size and statistical significance. The American Academy of Sleep Medicine (AASM) and the European Federation of Neurological Societies recommend modafinil as the first treatment option and methylphenidate as the second treatment option. The AASM also recommends amphetamine, methamphetamine, or dextroamphetamine as alternative treatments. During literature searches, no studies that directly examined the impact of treatment with modafinil, armodafinil, sodium oxybate (used with narcolepsy with cataplexy), or antidepressants on crash risk or driving performance were identified. Therefore, conclusions regarding treatment with these medications on crash risk and driving performance could not be made.

Currently available evidence suggests that amphetamines and/or methylphenidate are effective in improving symptoms of EDS in individuals with narcolepsy (quality of studies range from “moderate to low”). However, these improvements do not result in levels of daytime sleepiness that can be considered to be normal in the vast majority of individuals. Therefore, conclusions regarding to the impact of treatment with amphetamines, methylphenidate, or other related stimulant drugs on cognitive and psychomotor function among individuals with narcolepsy could not be made.

In January 2010, the FMCSA’s MRB recommended that individuals with narcolepsy be ineligible for a commercial driver’s license, even with treatment.

Discussion of Comments

FMCSA received one comment in this proceeding from a private citizen who did not support granting an exemption in the interest of public safety and the applicant's well-being. The commenter cites that the applicant's medical provider states that the applicant's current treatment has proven effective and that treatment continues without explicit determination by the medical provider that the current regimen has sufficiently remedied the applicant's medical condition such that it would not interfere with the ability to drive a CMV in the future. FMCSA acknowledges the commenter's concern. When evaluating a medical exemption application request, FMCSA considers the applicant's relevant medical information, however the Agency does not make a decision to grant or deny a medical exemption solely on the basis of an applicant's medical documentation.

III. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding this exemption application is based on an individualized assessment of the applicant's medical information, available medical and scientific data concerning narcolepsy, and any relevant public comments received.

IV. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting this exemption would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following applicant has been denied an exemption from the physical qualification standards in § 391.41(b)(8):

Sheila Bennett (TN)

The applicant has, prior to this notice, received a letter of final disposition regarding their exemption request. The decision letter fully outlined the basis for the denial and constitute final action by the Agency. The name of the individual published in this notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor,
Associate Administrator for Policy.

[FR Doc. 2022-09016 Filed: 4/27/2022 8:45 am; Publication Date: 4/28/2022]